MAR 31 2004

K033645

510(k) Summary of Safety and Effectiveness

Submitter

Name and address: GN Otometrics A/S
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Contact person: Per Pape Thomsen

Summary prepared: November 14, 2003

Device name

Common/Usual name: AudioDiagnostic Testing System
Trade/Proprietary name: OTOflex 100 type 1012
Classification name: Auditory Impedance Tester

Predicate devices

OTOflex is similar to the product Zodiac 901 Middle-Ear Analyzer (K910247) but differs in three ways: handheld operation powered by batteries, measurement with 1000 Hz probe tone and wireless computer interface.

Handheld operation powered by batteries is currently performed by Handtymp (K923072) and measurement with 1000 Hz probe tone is currently performed by GSI 2000 Middle Ear Analyzer (K000097).

Description

The OTOflex system consists of a charger unit, a handheld unit with built-in Bluetooth interface, a probe, a contra earphone, and software for installation on a PC. The probe and contra earphone is connected to the handheld unit. The handheld unit can be operated as a standalone device, as a desktop device when placed in the charger, or as a PC-based system from the software via a Bluetooth radio link.

The handheld unit is powered from batteries that are recharged when the unit is placed in the mains powered charger unit and two transducers for contra stimulus presentation are available: Probe and Insert phone.

Intended Use

The OTOflex 100 type 1012 is an auditory impedance tester that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. This device is also used to measure the acoustic reflex threshold and decay testing as well as eustachian tube function testing for intact and perforated tympanic membranes.

Technological Characteristics

Device Specifications	**OTOflex**	**Zodiac 901**
Safety compliance	EN 60601-1	EN 60601-1
Construction type	Handheld, Desktop, PC-based system	Desktop system
Power source	Batteries recharged from mains powered charger unit	Mains
Computer interface	Bluetooth radio link	RS232 cable connection
Supporting software	NOAH database SW	NOAH and PAX database SW

Safety

OTOflex is designed to provide safety to the patient as well as the user and complies with:

- EN 60601-1, UL 2601-1, CAN/CSA-C22.2 NO 601.1-90: Medical Electrical Equipment. Part 1: Generel requirements for safety
- EN 60601-1-1: Medical Electrical Equipment. Part 1: Generel requirements for safety. 1. Collateral standard: Safety requirements for medical electrical systems
- EN 60601-1-2: Medical Electrical Equipment. Part 1-2: Generel requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601-1-4: Medical Electrical Equipment. Part 1: Generel requirements for safety. 4. Collateral standard: Programmable electrical medical systems
- Medical devices Directive 93/42/EEC

OTOflex is designed, developed and manufactured according to:

- ISO 9001: Quality Management Systems – Requirements
- ISO13485: Quality Systems - Medical devices – Particular requirements for the application of ISO 9001

Effectiveness

The OTOflex is an Auditory Impedance Tester for replacement of an existing product of a technology type that is available and accepted in the market. OTOflex complies with product performance standards for impedance/admittance instruments: EN 61027 and ANSI S3.39.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2004

GN Otometrics A/S
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Denmark

Re: K033645
Trade/Device Name: OTOflex 100 Type 1012
Regulation Number: 21 CFR 874.1090
Regulation Name: Auditory impedance tester
Regulatory Class: Class II
Product Code: ETY
Dated: February 25, 2004
Received: March 2, 2004

Dear Mr. Thomsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

The OTOflex 100 type 1012 is an auditory impedance tester that is intended to change the air pressure in the external auditory canal and measure and graph the mobility characteristics of the tympanic membrane to evaluate the functional condition of the middle ear. This device is also used to measure the acoustic reflex threshold and decay testing as well as eustachian tube function testing for intact and perforated tympanic membranes.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K033645